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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,315	04/21/2004	Joel R. Studin	SDF 04-15	5670

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EXAMINER	
SHEIKH, HUMERA N	
ART UNIT	PAPER NUMBER
1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,315	STUDIN, JOEL R.	
	Examiner	Art Unit	
	Humera N. Sheikh	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 November 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

Receipt of the Response after Non-Final Office Action, Applicant's Arguments/Remarks and the Declaration under 37 C.F.R.1.131, all filed 11/07/08 is acknowledged.

Claims 17-25 are pending in this action. No claims have been amended. Claims 1-16 and 26-54 have previously been cancelled. Claims 17-25 remain rejected.

* * * * *

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Mantelle *et al.* (U.S. Pat. No. 6,562,363).

Youssefyeh *et al.* ('519) teach a method for the treatment of inflammation and pain associated with inflammatory dermatoses (eczema, psoriasis), gingivitis and acute injury with a composition of finely divided powder of safflower seed or its extract contained in a pharmaceutically acceptable carrier (see Abstract); (column 1, lines 10-18). Youssefyeh teach that the method of treatment for the relief of inflammation and/or pain associated with

inflammatory dermatoses such as eczema, urticaria, psoriasis and the like comprises topically administering a therapeutically effective amount of a finely divided powder of safflower seed or its extract sufficient to induce alleviation of signs, symptoms or causes of inflammation or pain in a pharmaceutically acceptable carrier (col. 11, line 49 – col. 12, line 58); (col. 13, line 53 – col. 14, line 7); (col. 22, line 64 – col. 24, line 13). Youssefyeh teach that for topical administration, the compositions may contain certain pharmaceutical and therapeutical agents either singularly or in combination of which suitable pharmaceutical/therapeutical agents disclosed include anti-inflammatory corticosteroids, such as progesterone, hydrocortisone, prednisone, triamcinolone and dexamethasone. Additional agents disclosed include anti-inflammatory analgesics, local anesthetics, antibacterial agents and antiseptic agents. It is also taught that the topical compositions can be in the forms of ointments, creams, lotions, solutions, dressings and patches and slow-release preparations and film-forming preparations (col. 14, lines 19-40); (col. 15, lines 29-60).

Topical formulations can be prepared by combining the finely divided safflower seed or its extract with conventional pharmaceutical carriers or diluents used in topical dry, liquid and cream formulations. Ointments and creams may be formulated with an aqueous or oil base with the addition of suitable thickening or gelling agents (col. 15, lines 29-60). Ointments, pastes, creams and gels may contain excipients such as cellulose derivatives and silicones (col. 15, lines 43-46).

A preferred form of topical delivery is film-forming materials loaded with finely divided powder of safflower seed or its extract. Suitable film-forming materials taught include cellulosic derivatives, such as methylcellulose, hydroxyethyl cellulose, hydroxypropyl cellulose and other

synthetic polymers (col. 15, line 61 – col. 17, line 19); and claim 12. Upon application, the formulation is deposited on the desired area and allowed to form a film, which by the presence of water in the skin environment, will allow slow delivery of the active agent onto the area being treated (col. 17, lines 20-23).

Applicants claim, "hardening the carrier into a tangible membrane" in claim 17. The instant claims differ from the prior art in that Youssefyeh do not specifically teach a "membrane" as instantly claimed. However, they nonetheless teach that the topical formulation is deposited onto the desired area and allowed to *form a film*, which will allow for slow release of active agent onto the treatment area. Thus, the "film" taught by Youssefyeh is functionally equivalent to the "membrane" claimed by Applicant.

Thus, the prior art teaches a method for treating immunological disorders as is instantly claimed. The method comprises topical administration of safflower oil in combination with a corticosteroid and a pharmaceutically acceptable carrier, whereby upon application, the formulation is deposited on the skin to form a film for the release of active agent onto the treatment area.

Youssefyeh each cellulose derivatives. (col. 15, lines 43-46). Youssefyeh do not teach that the film-forming carrier is nitrocellulose.

Mantelle *et al.* ('363) teach bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes and methods for topical administration of active ingredients. See Abstract. The bioadhesive compositions comprise a mixture of at least two bioadhesive materials (col. 2, lines 30-41). Particularly suitable bioadhesive materials taught

include cellulose materials such as nitrocellulose (col. 5, lines 40-55); (col. 6, lines 5-14). Mantelle teaches that such bioadhesive materials are effective for their swelling and absorption capabilities and provide enhanced and prolonged adherence to wet or moist surfaces, thereby increasing the effective penetration or absorption of the active ingredient (col. 4, lines 46-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the bioadhesive materials, such as nitrocellulose as taught by Mantelle within the delivery formulations of Youssefyeh et al. One of ordinary skill in the art would do so with a reasonable expectation of success because Mantelle teach that such bioadhesive materials (*i.e.*, nitrocellulose) are effective for their swelling and absorption capabilities and increase the effective penetration or absorption of an active ingredient. The expected result would an enhanced method for treating dermatological disorders with maximum absorption of active agents.

* * * * *

Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Brandt *et al.* (U.S. Pat. No. 6,627,216).

The teachings of Youssefyeh are discussed above. Youssefyeh do not teach that the film-forming carrier is nitrocellulose.

Brandt *et al.* ('216) teach fluid compositions that are coated onto the surface of a host animal and then dried to form a covering element, such as a transdermal bandage, patch or the

like (col. 1, lines 7-21). The fluid compositions include film-forming polymeric components of cellulosic polymers such as nitrocellulose. The polymer component (i.e., nitrocellulose) functions as a protective film covering (col. 10, line 46 – col. 11, line 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate cellulosic polymers, such as nitrocellulose as taught by Brandt within the delivery formulations of Youssefyeh et al. One of ordinary skill in the art would do so with a reasonable expectation of success because Brandt teach fluid compositions that dry to yield a coating whereby suitable materials that provide for the protective coating are nitrocellulose. The expected result would an improved method for treating dermatological disorders and conditions with enhanced delivery of active substances.

* * * * *

Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Herb *et al.* (U.S. Pat. No. 5,534,246).

The teachings of Youssefyeh are discussed above. Youssefyeh do not teach phenyltrimethicone and a vitamin.

Herb *et al.* ('246) teach topically-effective compositions comprising topically-active drugs that include dermatitis medications and psoriasis agents (see column 9, lines 46-51); (col. 10, lines 11-12). Herb *et al.* teach that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect or for adjusting the refractive index (col. 12, lines 41-54); (Claims 20 & 35). Vitamins can also be included as a suitable topically-effective compound (see Table 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dermatitic/psoriatic medications comprising the phenyltrimethicone organic compound and vitamins as taught by Herb *et al.* within the delivery formulations of Youssefyeh et al. One of ordinary skill in the art would do so with a reasonable expectation of success because Herb *et al.* explicitly teach that suitable and effective active agents for use in their formulation include vitamins as well as dermatitis and psoriasis medications to treat skin conditions and teach that organic compounds, such as phenyltrimethicone are added to the composition to provide aesthetically-based effects or alternatively, for the adjustment of refractive index values. The expected result would an enhanced method for treating dermatological disorders.

* * * * *

Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Mantelle *et al.* (U.S. Pat. No. 6,562,363).

Mantelle ('070) teaches flexible, finite, bioadhesive compositions for topical application comprising a therapeutically effective amount of a pharmaceutical agent(s), a pharmaceutically acceptable carrier and a solvent for the pharmaceutical agent(s) in the carrier and methods of administering the pharmaceutical agents (see Abstract); (col. 1, lines 18-34); (col. 4, line 24 – col. 5, line 62).

The composition when administered topically, for example to an area of the skin, delivers a pharmaceutical agent or a combination of agents to produce a local or systemic effect over a prolonged period of time (col. 5, line 65 – col. 6, line 3).

Suitable active agents disclosed for use in the invention include anti-inflammatory drugs, corticosteroids and the like (col. 23, line 32 – col. 41, line 39); claim 4; Examples 30-32.

Suitable adhesive carriers are disclosed at column 12, lines 55-65 and include cellulose derivatives, silicones.

Mantelle does not teach that the film-forming carrier is nitrocellulose.

Mantelle *et al.* ('363) teach bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes and methods for topical administration of active ingredients. See Abstract. The bioadhesive compositions comprise a mixture of at least two bioadhesive materials (col. 2, lines 30-41). Particularly suitable bioadhesive materials taught include cellulose materials such as nitrocellulose (col. 5, lines 40-55); (col. 6, lines 5-14). Mantelle teaches that such bioadhesive materials are effective for their swelling and absorption capabilities and provide enhanced and prolonged adherence to wet or moist surfaces, thereby increasing the effective penetration or absorption of the active ingredient (col. 4, lines 46-65).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the bioadhesive materials, such as nitrocellulose as taught by Mantelle ('363) within the formulations of Mantelle ('070). One of ordinary skill in the art would do so with a reasonable expectation of success because Mantelle teach that such bioadhesive materials (*i.e.*, nitrocellulose) are effective for their swelling and absorption capabilities and increase the effective penetration or absorption of an active ingredient. The expected result would an enhanced method for treating dermatological disorders with maximum absorption of active agents.

* * * * *

Claims 17-21, 23 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Brandt *et al.* (U.S. Pat. No. 6,627,216).

The teachings of Mantelle ('070) are discussed above. Mantelle do not teach that the film-forming carrier is nitrocellulose.

Brandt *et al.* ('216) teach fluid compositions that are coated onto the surface of a host animal and then dried to form a covering element, such as a transdermal bandage, patch or the like (col. 1, lines 7-21). The fluid compositions include film-forming polymeric components of cellulosic polymers such as nitrocellulose. The polymer component (i.e., nitrocellulose) functions as a protective film covering (col. 10, line 46 – col. 11, line 9).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate cellulosic polymers, such as nitrocellulose as taught by Brandt within the formulations of Mantelle. One of ordinary skill in the art would do so with a reasonable expectation of success because Brandt teach fluid compositions that dry to yield a coating whereby suitable materials that provide for the protective coating are nitrocellulose. The expected result would an improved method for treating dermatological disorders and conditions with enhanced delivery of active substances.

* * * * *

Claims 22 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mantelle (U.S. Pat. No. 5,446,070) in view of Herb *et al.* (U.S. Pat. No. 5,534,246).

The teachings of Mantelle ('070) are discussed above. Mantelle does not teach phenyltrimethicone.

Herb *et al.* ('246) teach topically-effective compositions comprising topically-active drugs that include dermatitis medications and psoriasis agents (see column 9, lines 46-51); (col. 10, lines 11-12). Herb *et al.* teach that nonvolatile organic compounds, such as phenyltrimethicone can also be added to the compositions to provide an aesthetic effect or for adjusting the refractive index (col. 12, lines 41-54); (Claims 20 & 35).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the dermatitic/psoriatic medications comprising the phenyltrimethicone organic compound as taught by Herb *et al.* within the formulations of Mantelle. One of ordinary skill in the art would do so with a reasonable expectation of success because Herb *et al.* explicitly teach that suitable and effective active agents for use in their formulation include dermatitis and psoriasis medications to treat skin conditions and teach that organic compounds, such as phenyltrimethicone are added to the composition to provide aesthetically-based effects or alternatively, for the adjustment of refractive index values. The expected result would an enhanced composition and method for treating skin disorders.

Response to Arguments

Applicant's arguments filed 11/07/08 have been fully considered but they are not persuasive.

- **Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Mantelle *et al.* (U.S. Pat. No. 6,562,363).**

Applicant argued, "Youssefyeh does not disclose or teach use of nitrocellulose as the film-forming carrier. Applicant submits herewith Rule 37 C.F.R.1.131 Declaration to overcome Mantelle."

These arguments were not persuasive. While Youssefyeh do not teach that the film-forming carrier is nitrocellulose, the secondary reference of Mantelle ('363) clearly remedies this deficiency by their teaching of bioadhesive compositions in a flexible, finite form for topical application to skin or mucous membranes and methods for topical administration of active ingredients. The bioadhesive compositions comprise a mixture of at least two bioadhesive materials (col. 2, lines 30-41). Particularly suitable bioadhesive materials taught include cellulose materials such as nitrocellulose (col. 5, lines 40-55); (col. 6, lines 5-14). Mantelle teaches that such bioadhesive materials are effective for their swelling and absorption capabilities and provide enhanced and prolonged adherence to wet or moist surfaces, thereby increasing the effective penetration or absorption of the active ingredient (col. 4, lines 46-65).

Regarding the Declaration under 37 C.F.R.1.131 filed 11/07/08, the Declaration has been fully considered but is not sufficient to overcome the Mantelle ('363) reference. The Declaration under 1.131 is insufficient to show the invention in 1996. The scope of the declaration presented does not show establishment of the claimed invention. There is present only one amount, one carrier, with no discussion of putting the carrier on a skin that has the diseases in 1996.

- **Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Brandt *et al.* (U.S. Pat. No. 6,627,216).**

Applicant argued, "Youssefyeh does not disclose or teach use of nitrocellulose as the film-forming carrier. Brandt is no longer an effective reference against the invention as claimed. Applicant submits herewith Rule 37 C.F.R.1.131 Declaration to overcome Youssefyeh in view of Brandt."

These arguments were not persuasive. The teachings of Youssefyeh are discussed above. Youssefyeh do not teach that the film-forming carrier is nitrocellulose, however the secondary reference of Brandt clearly remedies this deficiency by their teaching of fluid film-forming compositions that incorporate cellulosic polymers such as nitrocellulose. Thus, Brandt amply remedies the deficiency of Youssefyeh. Regarding the Declaration under 37 C.F.R.1.131 filed 11/07/08, the Declaration has been fully considered but is not sufficient to overcome the Brandt reference. The Declaration under 1.131 is insufficient to show the invention in 1996. The scope of the declaration presented does not show establishment of the claimed invention. There is present only one amount, one carrier, with no discussion of putting the carrier on a skin that has the diseases in 1996.

- **Youssefyeh *et al.* (U.S. Pat. No. 5,968,519) in view of Herb *et al.* (U.S. Pat. No. 5,534,246).**

Applicant argued, "Youssefyeh does not disclose or teach use of nitrocellulose as the film-forming carrier. Herb does not disclose or teach use of nitrocellulose as the film-forming carrier."

These arguments were not persuasive. The teachings of Youssefyeh are discussed above. The Herb reference was relied upon for the teaching of phenyltrimethicone and a vitamin, which it sufficiently teaches in topically-effective compositions. See col. 12, lines 41-54. Thus, Brandt amply remedies the deficiency of Youssefyeh.

Regarding the Declaration under 37 C.F.R.1.132, the declaration must present facts that represent a showing commensurate in scope with the claimed invention, taking into consideration the teachings of the prior art. Here the art is well aware of the use of carriers and Applicant presents data in an attempt to show some unexpected result over the prior art. A review of Exhibit A indicates that there is no data that would represent the generic concept claimed. Specifically the claims are drawn to a steroid, whereas only a single corticosteroid has been presented. The amount of active ingredient compared in Applicant's data has not been claimed in the claims, nor has Applicant presented claims that restrict the time intervals necessary for the unexpected result such as 1 hr., 2 hrs. or 4 hrs. limited by the declaration. Furthermore there is no indication that the subject had scar tissue, psoriasis, eczema, or other cutaneous maladies. The Declaration, after a thorough reading, is too limited to establish any unexpected results given the generic claims presented.

- **Mantelle (U.S. Pat. No. 5,446,070) in view of Mantelle *et al.* (U.S. Pat. No. 6,562,363):**

Applicant argued, "Mantelle ('070) does not teach that the film-forming carrier is nitrocellulose. The Rule 37 C.F.R.1.131 Declaration overcomes Mantelle ('363)."

Applicant's arguments were not persuasive. The Mantelle reference teaches bioadhesive compositions comprising a mixture of at least two bioadhesive materials (col. 2, lines 30-41).

Particularly suitable bioadhesive materials taught include cellulose materials such as nitrocellulose. Regarding the Declaration under 37 C.F.R.1.131 filed 11/07/08, the Declaration has been fully considered but is not sufficient to overcome the Mantelle ('363) reference. The Declaration under 1.131 is insufficient to show the invention in 1996. The scope of the declaration presented does not show establishment of the claimed invention.

- **Mantelle (U.S. Pat. No. 5,446,070) in view of Brandt *et al.* (U.S. Pat. No. 6,627,216).**

Applicant argued, "Mantelle ('070) does not teach that the film-forming carrier is nitrocellulose. Brandt is no longer an effective reference against the invention as claimed." These arguments were not persuasive.

The secondary reference of Brandt clearly remedies the deficiency of Mantelle by their teaching of fluid film-forming compositions that incorporate cellulosic polymers such as nitrocellulose. Regarding the Declaration under 37 C.F.R.1.131 filed 11/07/08, the Declaration has been fully considered but is not sufficient to overcome the Brandt reference. The Declaration under 1.131 is insufficient to show the invention in 1996. The scope of the declaration presented does not show establishment of the claimed invention. There is present only one amount, one carrier, with no discussion of putting the carrier on a skin that has the diseases in 1996.

- **Mantelle (U.S. Pat. No. 5,446,070) in view of Herb *et al.* (U.S. Pat. No. 5,534,246).**

Applicant argued, "Mantelle does not disclose or teach use of nitrocellulose as the film-forming carrier. Herb does not disclose or teach use of nitrocellulose as the film-forming carrier."

These arguments were not persuasive. The Herb reference was relied upon for the teaching of phenyltrimethicone and a vitamin, which it sufficiently teaches in topically-effective compositions. See col. 12, lines 41-54. Thus, Herb amply remedies the deficiency of Mantelle based on their teaching of phenyltrimethicone and a vitamin.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

--No claims are allowed at this time.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Humera N. Sheikh whose telephone number is (571) 272-0604.

The examiner can normally be reached on Monday, Tuesday, Thursday and Friday during regular business hours.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have any questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Humera N. Sheikh/

Primary Examiner, Art Unit 1615

hns

January 21, 2009